

Analysis of the Supply Chain in Managing Second-Line Anti-TB Drugs at State Drug Stores: An Observational Study

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Abstract:

Introduction: MDR-TB is a global health threat requiring uninterrupted access to second-line TB drugs for successful treatment. Inefficiencies in the supply chain can disrupt access, prompting this investigation into stockout factors at an SDS in Maharashtra, India.

Objectives: Study investigates the drug supply chain at the State Drug Store (SDS). Measure the stock situation for second-line anti-TB drugs at the SDS. By analyzing stakeholder perspectives, the study will explore factors contributing to gaps involved.

Materials and Methods: A cross-sectional study was conducted from October 2023 to January 2024 in one of three State Drug Stores (SDS) located in Maharashtra, India. Maharashtra has 3 SDS and to ensure anonymity, the SDS involved in the study are labeled as SDS1. Five-year retrospective data of the TB drug supply chain from the Central TB Division website (quantitative) and primary data from stakeholders (interviews, document review, TB program survey) were analyzed using Power Query (quantitative) and thematic analysis (qualitative) to identify trends, challenges, and stakeholder perspectives.

Results: The key findings of the study are stockouts of medicines, expiry of drugs and delay in disposal of expired drugs, insufficient fund allotment for local purchases, and inadequate quantities received from the Central TB Division (CTD).

Conclusion: State Drugs State in total has been maintained well and it is crucial to recognize the ongoing efforts of the SDS to navigate these difficulties and ensure patient access to vital medications. Moving forward, implementing the proposed solutions like demanding funds from higher authorities to start local purchases can strengthen the SDS's ability to provide uninterrupted access to essential medications.

Keywords: Nikshay Aushadhi, Supply Chain, Indent Quantity

1. Introduction

According to the World Health Organization (WHO), pharmaceuticals constitute the second-highest expenditure in a country's healthcare system, surpassed only by staff costs. Governments allocate a

substantial portion of their public sector health budget—ranging from 40 to 60 percent—toward procuring medicines.^{[3][4]} Despite such significant investments, essential medicines remain inaccessible to one-third of the global population, with this figure rising to one-half in Asia and Africa.^[5] This situation is largely attributed to resource mismanagement, with estimates suggesting that up to 70 % of resources are squandered in countries due to inadequate drug management systems.^[6]

The supply chain is the process of moving drugs from the point of origin or manufacturer to the point of consumption or a service delivery point done through web-based real-time software, i.e. Nikshay-Aushadhi. A Procurement and Supply Chain Management (PSM) Unit has been established at the Central TB Division (CTD) as shown in Figure 1. Drugs are issued from the Government Medical Store Depots (GMSDs)/ Central Medical Store Society (CMSS) warehouses to the State Drug Stores (SDS) for onward distribution to the districts. GMSDs/ CMSS take about 21 days to dispatch the drugs to the State Drug Store or districts.^[7]

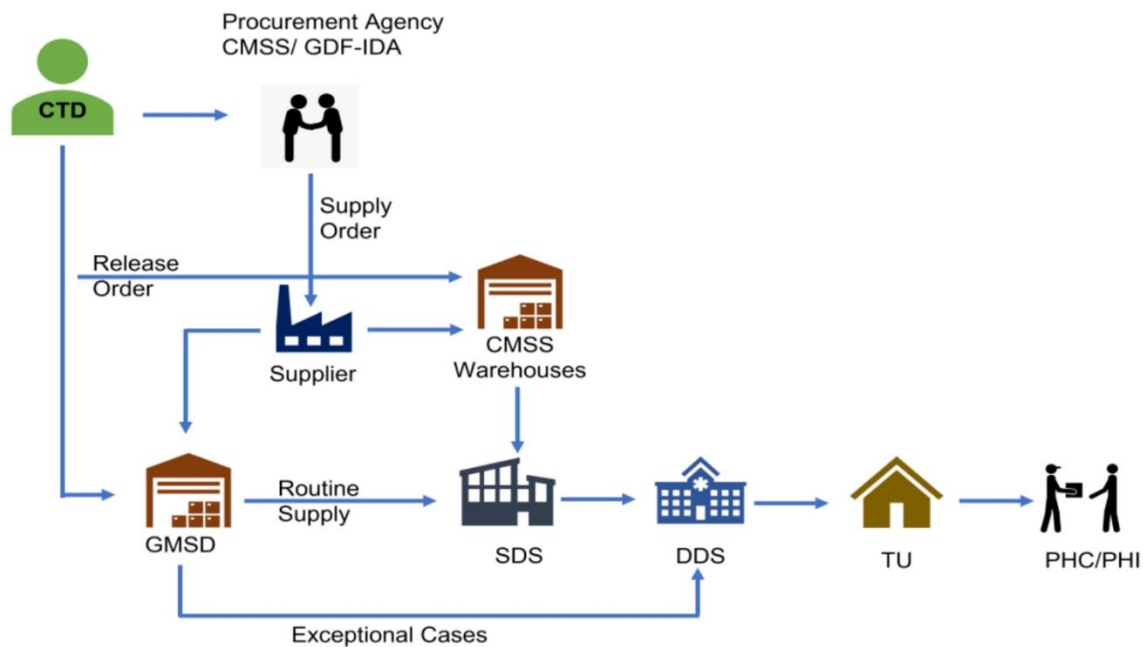


Figure 1: Drug Distribution of anti-TB drugs from CTD to PHC/PHI

Rationale:

A study by L.E.M Koomen et al., 2018 found that stockouts of second-line anti-TB drugs were a major barrier to MDR-TB treatment completion in South Africa.^[1] Joint Workshop by the Institute of Medicine, the Indian National Science Academy, and the Indian Council of Medical Research, 2012 found that inefficiencies in the supply chain for second-line anti-TB drugs contributed to the development of drug resistance in India.^[2] A paucity of research exists regarding the specific prevalence of stockouts for second-line anti-tuberculosis (TB) medications within the Indian healthcare system. This lack of knowledge hinders the development of effective strategies to manage MDR-TB. The present study aims to bridge this critical knowledge gap by investigating the prevalence of stockouts for second-line anti-TB drugs at State Drug Stores (SDS) in Maharashtra, India.

Objectives:

Studies have shown that stockouts of anti-TB medications can lead to treatment interruptions, poorer treatment outcomes, and increased mortality rates among TB patients. Additionally, stockouts can

contribute to the development of drug-resistant TB strains, as patients who are unable to complete their full course of treatment are more likely to develop resistance to the medications they are taking. Keeping this in mind the study aims to

1. Investigates the drug supply chain at the SDS, focusing on second-line anti-TB drugs.
2. Measure the stock situations for second-line anti-tuberculosis medications at the SDS.
3. By analyzing stakeholder perspectives, the study will explore factors contributing to gaps in managing the second-line anti-TB drug supply chain at SDS.

Public Health Implications – An optimally functioning supply chain for second-line anti-tuberculosis medications has the potential to significantly transform the landscape of MDR-TB management by uninterrupted patient access to these life-saving drugs, facilitating improved treatment completion rates, diminished treatment failure occurrences, and a subsequent reduction in mortality. By effectively addressing stockout issues, we can pave the way for the establishment of a more robust healthcare system, ultimately contributing to a healthier populace and a demonstrably reduced burden of MDR-TB.

1. Materials and Methods

Study Design: A cross-sectional study with a mixed methods approach was conducted from October 2023 to January 2024 (cross-sectional) and retrospective data for the past five years (2018-2023) was also analyzed.

Data Sources

Secondary data: Retrospective data on the anti-tuberculosis (TB) drug supply chain in the state drug store (SDS) was obtained from the Central TB Division website, spanning the past five years. This served as quantitative data for trend analysis and context understanding.

Primary data

1. **Unstructured interviews:** Stakeholders involved in the TB drug supply chain at SDS, including pharmacists, logistics personnel, and program managers, were interviewed using an open-ended format to gather qualitative insights into challenges, processes, and practices.
2. **Document review:** Documents related to the TB drug supply chain at SDS, such as standard operating procedures, inventory records, and reports, were reviewed to support and verify the findings from the interviews.
3. **Survey:** A survey based on the National TB Elimination Programme guidelines was conducted, likely targeting specific groups within the TB program for their perspectives.

Data Analysis

Quantitative data: Power Query, a data analysis tool, was used to analyze the retrospective data from the Central TB Division website.

Qualitative data: Thematic analysis was employed to analyze the data from the unstructured interviews and document reviews. This involved identifying recurring themes and patterns within the data and providing insights into the experiences and perspectives of stakeholders.

Overall, the study design combined retrospective data analysis with qualitative methods to provide a comprehensive understanding of the current state and challenges within the TB drug supply chain at SDS.

Inclusion and Exclusion Criteria: The global rise in multidrug-resistant TB (MDR-TB) poses a significant challenge to effective tuberculosis control. India has the second highest MDR-TB burden globally, with over four times higher treatment resistance and more than ten times higher MDR-TB development probability in previously treated individuals compared to untreated cases. [8] Considering the burden of resistant TB in India second-line anti-TB drugs were included in the study whereas first-line

anti-TB drugs and other items such as treatment-related supplies, diagnostics, and stationery and printing, etc were excluded from the study.

The Institutional Ethical Committee ethically approved the study.

2. Results

Drug Supply Chain at State Drug Store - Each state should have one fully operational State Drug Store (SDS) for every 5 crore population. The population of Maharashtra was estimated to be over 124 million, which is equivalent to 12.4 crores, which justifies the existence of 3 SDSs in Maharashtra. Figure 1: shows that three State Drug Stores (SDS), located in Pune, Nagpur, and Mumbai, manage the distribution network for anti-tuberculosis drugs within Maharashtra, India. This system ensures accessibility of these vital medications across the state. SDS Pune supplies anti-TB drugs to 34 districts. Nagpur SDS caters to 17 districts. Mumbai, a high-population area, has its dedicated branch, SDS Mumbai, which focuses on distributing these medications within its 24 districts.

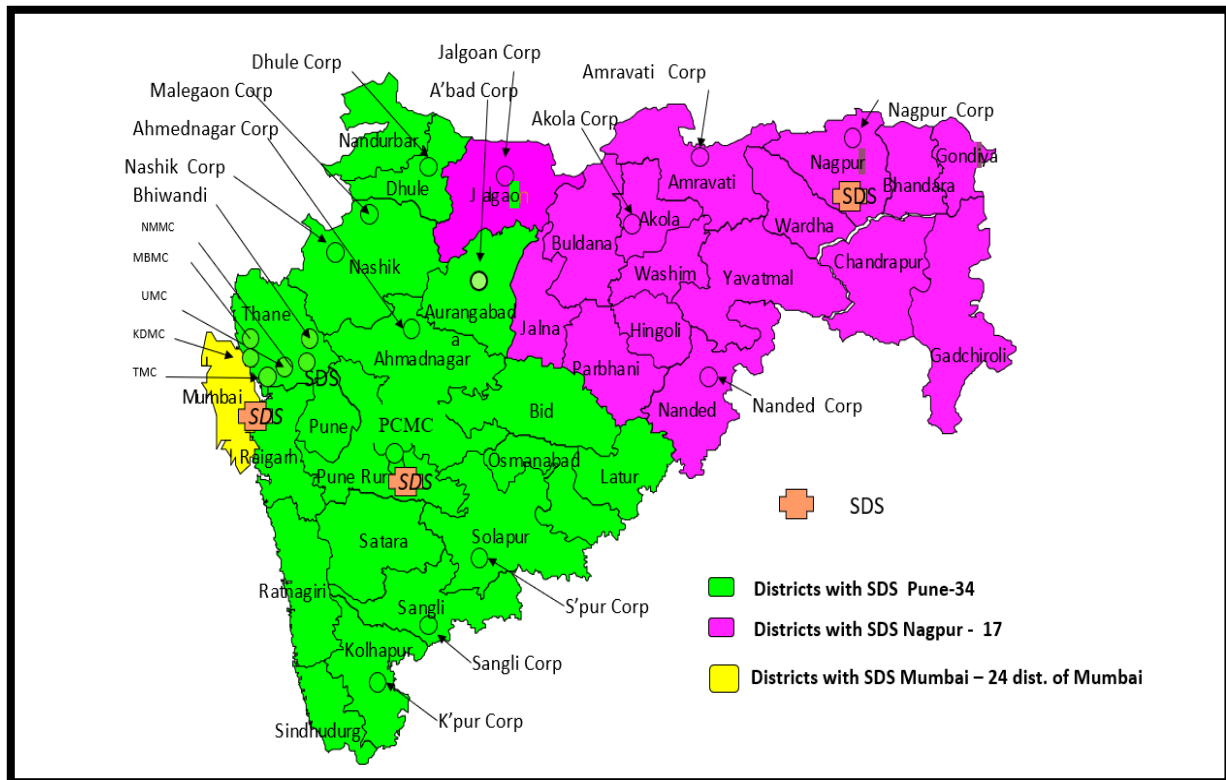


Figure 2: distribution network for anti-tuberculosis drugs within Maharashtra, India

SOP followed for distribution of drugs at State Drug Store (SDS) 1 :

1. Initiating Distribution:

Drug distribution starts upon receiving demands from districts through the State Drug Store (SDS). All districts along a specific route, like SATARA, SANGLI, KOLHAPUR, RATNAGIRI, and SINDHUDURG, are collectively considered for sequential distribution. The distribution van follows this route, starting with SATARA. Initiating drug distribution for SDS-dependent districts requires demands from all districts along a designated route, aligned with Nikshay Aushadhi indent requirements. Anticipated dispatch dates are communicated monthly, ensuring timely indents through official letters.

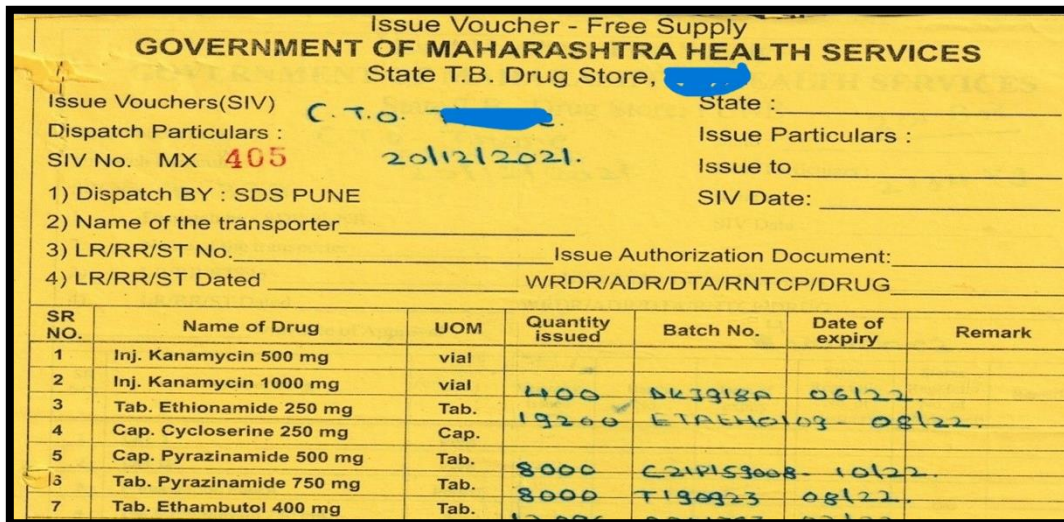
Medicines are prepared upon receiving all indents, and quantities are verified on Nikshay Aushadhi by the pharmacy officer based on current requirements.

2. Picking and Packing

Medicines are selected following the First Expiry First Out (FEFO) principle from individually labeled storage rooms, gathered from racks prioritizing the nearest expiry for dispatch. These loose medicines are repackaged into transport-ready carton boxes. Each box, assigned to a district or city tuberculosis center, is weighed using a digital scale, with the total recorded for billing. Finally, boxes are labeled and stacked on pallets in the dispatch area.

3. Dispatch and Follow-up

The authorized courier agency is promptly informed through phone and email to collect and transport the medicine batch to the designated CTO/DTO. Before the transfer, a detailed manual issue voucher is prepared for each DTO/CTO from the voucher book, encompassing vital information such as quantities, batch numbers, expiry dates, and the total count of medicine boxes, as depicted in Figure 3.



Issue Voucher - Free Supply
GOVERNMENT OF MAHARASHTRA HEALTH SERVICES
State T.B. Drug Store, [redacted]

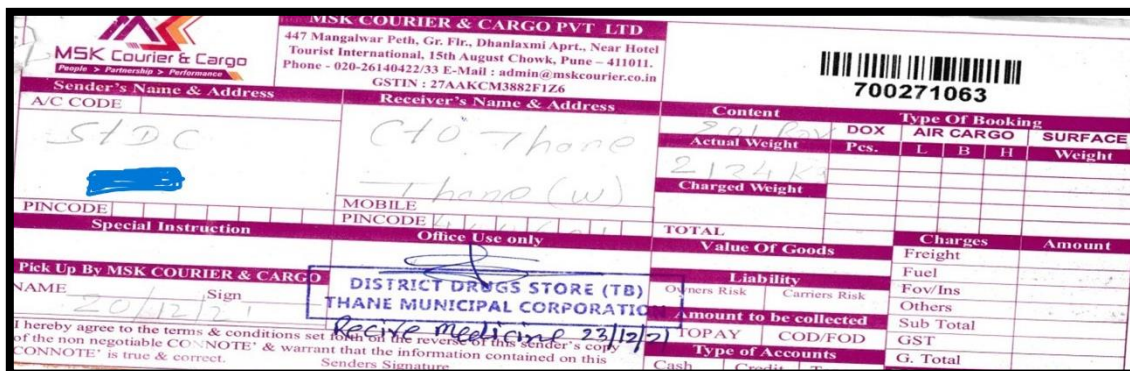
Issue Vouchers(SIV) C.T.O. [redacted] State : _____
 Dispatch Particulars : _____ Issue Particulars : _____
 SIV No. MX 405 20/12/2021. Issue to _____
 SIV Date: _____

1) Dispatch BY : SDS PUNE
 2) Name of the transporter _____
 3) LR/RR/ST No. _____ Issue Authorization Document: _____
 4) LR/RR/ST Dated _____ WRDR/ADR/DTA/RNTCP/DRUG _____

SR NO.	Name of Drug	UOM	Quantity issued	Batch No.	Date of expiry	Remark
1	Inj. Kanamycin 500 mg	vial				
2	Inj. Kanamycin 1000 mg	vial	400	AK3918A	06/22	
3	Tab. Ethionamide 250 mg	Tab.	19200	ETACHA103	08/22	
4	Cap. Cycloserine 250 mg	Cap.				
5	Cap. Pyrazinamide 500 mg	Tab.	8000	C24P153008	10/22	
6	Tab. Pyrazinamide 750 mg	Tab.	8000	T190923	08/22	
7	Tab. Ethambutol 400 mg	Tab.				

Figure 3: Scan Copy of Issue Voucher

Upon dispatch, pharmacy officers at receiving districts are informed, and a tracking number is obtained from the courier agency for monitoring (Figure 4).



MSK COURIER & CARGO PVT LTD
 447 Mangalwar Peth, Gr. Flr., Dhanlaxmi Apt., Near Hotel Tourist International, 15th August Chowk, Pune - 411011.
 Phone - 020-26140422/33 E-Mail : admin@mskcourier.co.in GSTIN : 27AAKCM3882F1Z6

Sender's Name & Address: STDC [redacted]
 Receiver's Name & Address: CTO, Thane Thane (W)

Content: 201 boxes
 Actual Weight: 2124 kg
 Charged Weight: _____

Barcode: 700271063

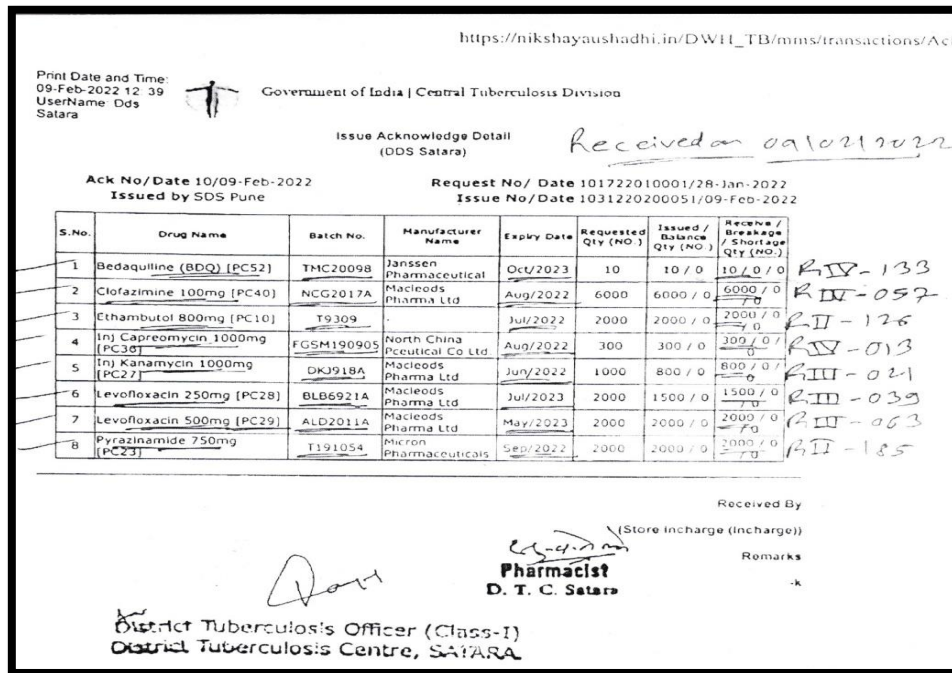
Pick Up By MSK COURIER & CARGO: 20/12/21
 Sign: [Signature]
 District Drugs Store (TB) Thane Municipal Corporation
 Receive medicine 23/12/21

Charges: Freight, Fuel, Fov/Ins, Others, Sub Total, GST, G. Total

Figure 4: Scan copy of courier agency receipt

The dispatched medicines are manually recorded in the issue register for internal tracking. Consistent follow-up with the courier agency and receiving pharmacy officers ensures timely delivery. Upon reaching

the CTO/DTO store, follow-up is conducted to receive acknowledgment from all CTO/DTOs as shown in figure 5.



Print Date and Time: 09-Feb-2022 12:39
 Username: Dds Satara
 Government of India | Central Tuberculosis Division
 Issue Acknowledgement Detail (DDS Satara)
 Ack No./Date: 10/09-Feb-2022 Issued by: SDS Pune
 Request No./Date: 101722010001/28-Jan-2022
 Issue No./Date: 1031220200051/09-Feb-2022

S.No.	Drug Name	Batch No.	Manufacturer Name	Expiry Date	Requested Qty (NO.)	Issued / Balance Qty (NO.)	Receive / Breakage / Shortage Qty (NO.)	Remarks
1	Bedaquiline (BDQ) [PC52]	TMC20098	Janssen Pharmaceutical	Oct/2023	10	10 / 0	10 / 0 / 0	R II - 133
2	Clofazimine 100mg [PC40]	NGC2017A	Macleods Pharma Ltd	Aug/2022	6000	6000 / 0	6000 / 0	R II - 057
3	Ethambutol 800mg [PC10]	T9309		Jul/2022	2000	2000 / 0	2000 / 0	R II - 126
4	Inj Capreomycin 1000mg [PC30]	FGSM190905	North China Pceutical Co Ltd	Aug/2022	300	300 / 0	300 / 0	R II - 013
5	Inj Kanamycin 1000mg [PC27]	DK918A	Macleods Pharma Ltd	July/2022	1000	800 / 0	800 / 0 / 0	R II - 021
6	Levofloxacin 250mg [PC28]	BLB6921A	Macleods Pharma Ltd	Jul/2023	2000	1500 / 0	1500 / 0	R II - 039
7	Levofloxacin 500mg [PC29]	ALD2011A	Macleods Pharma Ltd	May/2023	2000	2000 / 0	2000 / 0	R II - 063
8	Pyrazinamide 750mg [PC23]	T191054	Micron Pharmaceuticals	Sep/2022	2000	2000 / 0	2000 / 0	R II - 185

Received By: *[Signature]*
 (Store Incharge (Incharge))
 Pharmacist
 D. T. C. Satara
 District Tuberculosis Officer (Class-I)
 District Tuberculosis Centre, SATARA

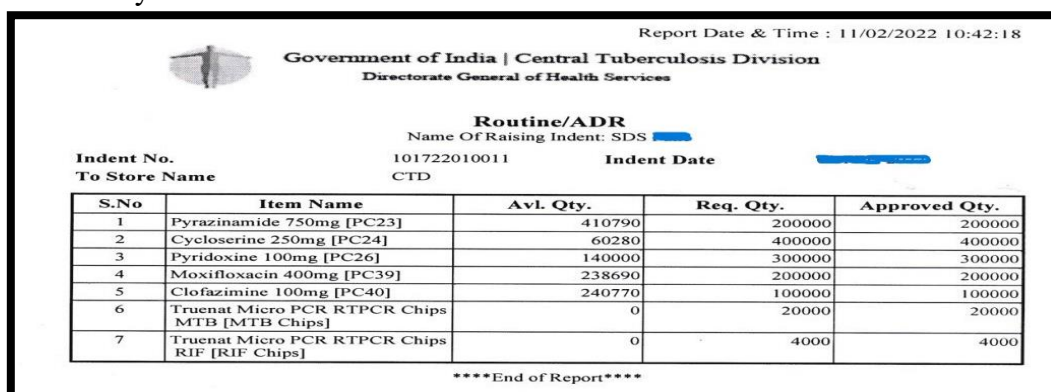
Figure 5: Issue Acknowledgement from DDS Satara

1. Excess Stock Management and Repurposing

Drug Transfer Authorization (DTA) is initiated when a district accumulates excess medication beyond immediate needs, facilitating the transfer of surplus medicines to another district with higher demand to optimize resource allocation and prevent wastage. In the case of unused or expired medications, such as Bedaquiline tablets returned from districts due to patient death or unforeseen circumstances, a reprocessing mechanism is employed through Nikshay Aushadhi. At the State Drug Store level, these medications may be either repackaged into new, full-dose containers like 188-tablet Bedaquiline jars for future use or disposed of following proper safety protocols.

2. Receiving and Recording Stock from Central Agency

Upon indenting with the Central TB Division (CTD) in New Delhi (Figure 6), the State Drug Store promptly receives a release order (Figure 7) specifying the allocated medications, with an expectation of delivery within 21 days.



Report Date & Time : 11/02/2022 10:42:18
 Government of India | Central Tuberculosis Division
 Directorate General of Health Services
 Routine/ADR
 Name Of Raising Indent: SDS
 Indent No. 101722010011 Indent Date
 To Store Name CTD

S.No	Item Name	Avl. Qty.	Req. Qty.	Approved Qty.
1	Pyrazinamide 750mg [PC23]	410790	200000	200000
2	Cycloserine 250mg [PC24]	60280	400000	400000
3	Pyridoxine 100mg [PC26]	140000	300000	300000
4	Moxifloxacin 400mg [PC39]	238690	200000	200000
5	Clofazimine 100mg [PC40]	240770	100000	100000
6	Truenat Micro PCR RTPCR Chips MTB [MTB Chips]	0	20000	20000
7	Truenat Micro PCR RTPCR Chips RIF [RIF Chips]	0	4000	4000

****End of Report****

Figure 6: Scan copy of Indent raised

No. T-18018/30/2018-TB
Ministry of Health & Family Welfare
(Central TB Division)
RELEASE ORDER (CMSS/2022/FEB/01)

Jeevan Vihar, New Delhi – 110001
Dated: 2nd Feb 2022

Services Society
Body under MoHFW, Govt
New Yuvak Kendra, 8, Teen Murti Road,
New Delhi- 110021

of anti-TB drugs to State- regarding
anti TB drugs from CMSS Warehouses to NTEP-State Drug Store, as per the allocation below:

State Drug Store	PC-28 Levofloxacin 250mg	PC-29 Levofloxacin 500mg	PC-31 Pyridoxine 50mg	PC-38 Linezolid 600mg	PC-7 Isoniazid 100mg	PC-11 Isoniazid 300mg	PC-24 Cycloserine 250mg	PC-39 Moxifloxacin 400 mg	PC-23 Pyrazinamide- 750mg	PC-26 Pyridoxine- 100mg	PC-10 Ethambutol 800mg	PC-20 Ethionamide 250mg
(To)	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.	Tab.
SDS- Hyderabad	50,000	50,000	50,000	1,000	-	-	-	-	-	-	-	-
SDS- Bhopal	-	-	-	-	-	150,000	-	-	-	-	-	-
SDS- Patna	-	-	-	-	-	-	400,000	200,000	-	300,000	-	-
SDS- Lucknow	-	-	-	-	-	-	-	-	150,590	-	-	-
SDS- Bhubaneswar	-	-	-	-	8,000	10,000	2,000	500	-	-	1,000	2,000

(Dr. Alok Mathur)
Addl. DDG-TB
Central TB Division

Figure 7: Scan copy of release copy from CTD

Upon receiving the medicines, all batches undergo verification against the issue voucher and are organized on storage racks following the FEFO principle. Acknowledgment of receipt is recorded online in Nikshay Aushadhi (Figure 8). The physical stock is meticulously entered into the Receipt Register (Figure 9) and the issue register for comprehensive record-keeping.

Print Date and Time: 17-Feb-2022 15: 44
UserName: Sds

Government of India Central Tuberculosis Division

Issue Acknowledge Detail
(SDS)

Ack No/Date 10/17-Feb-2022 Request No/ Date 101722020002(1)/10-Feb-2022
Issued by CW Hyderabad Issue No/Date 1031220200004/15-Feb-2022

S.No.	Drug Name	Batch No.	Manufacturer Name	Expiry Date	Requested Qty (NO.)	Issued / Balance Qty (NO.)	Receive / Breakage / Shortage Qty (NO.)
1	Pyrazinamide 750mg [PC23]	JK19501	-	May/2023	150590	71150 / 0	71150 / 0
2	Pyrazinamide 750mg [PC23]	JK19503	-	Jul/2023	150590	79440 / 0	79440 / 0

Received By
(SDS)

Remarks
SDS

II/139(2022)

Figure 8: Scan copy of Acknowledgement of medicines received from CTD

Date	LR No & date	Name of the transporter	No of boxes	RO No of date	order by	by whom	Invoice no & date	Name of the medicine	Quantity	Batch no	mfy date	Expiry date	LE No & Regn.
8.11.2023 488	46180 3.11.2023	Aashirwad Enterprises Logistics & Transport Contractors	60	T-18018/30/2018-TB Part-I dt. 2.11.2023 [CMSS/2023/Nov/1]	CTD New Delhi	CU Man Mumbai	103123110434 3.11.2023	Cap. Cyclohexime 250mg	86860	ECB5230224	10.23	9.25	II/57 (2023)
									640	JDC T-308	9.23	8.25	II/57 (2023)
									87500	J Duncan Healthcare Pvt Ltd			
								Tb Linezolid 600mg	52500	LZDT1112	9.23	8.26	III/55 (2023)
										[Unicare India Pvt Ltd]			
3.11.23 489	46180 8.11.2023	Aashirwad Enterprises Logistics & Transport Contractors	60	T-18018/30/2018-TB Part-I dt. 2.11.2023 [CMSS/2023/Nov/1]	CTD New Delhi	CU Man Mumbai	103123110434 3.11.2023	Tb Delamanid 50mg	45972	3181587	3.23	8.27	III/95 (2023)
									4428	3181657	3.23	8.27	III/95 (2023)
									50400	[Mylan Laboratories Limited]			
8.11.23 490	20000807488 31.10.2023	DTDC Express Limited	50	T-18018/30/2018-TB Part-I dt. 26.10.2023 [CMSS/2023/Oct/18]	CTD New Delhi	CU Lucknow	1031231102245 31.10.2023	Tb Linezolid 600mg	84750	LZDT1110	9.23	8.26	III/56 (2023)
									15250	LZDT1111	9.23	8.26	III/56 (2023)
									100,000	[Unicare India Limited]			

Figure 9: Scan copy of Stock receipt register

Stock situation of second line anti-TB drugs at SDS 1 - There are 17 second-line anti-TB drugs, of which 11 are available in Maharashtra as state stock and 06 are not available. As shown in Figure 10, SDS 3 has 68% of the stock, whereas SDS 2 has only 7% of the stock. SDS 1 has the highest stock of Linezolid 600mg, Ethionamide 250mg, Clofazimine 100mg, and Clofazimine 50mg. A further detailed breakdown of the state stock of medications is given in Figure 11.

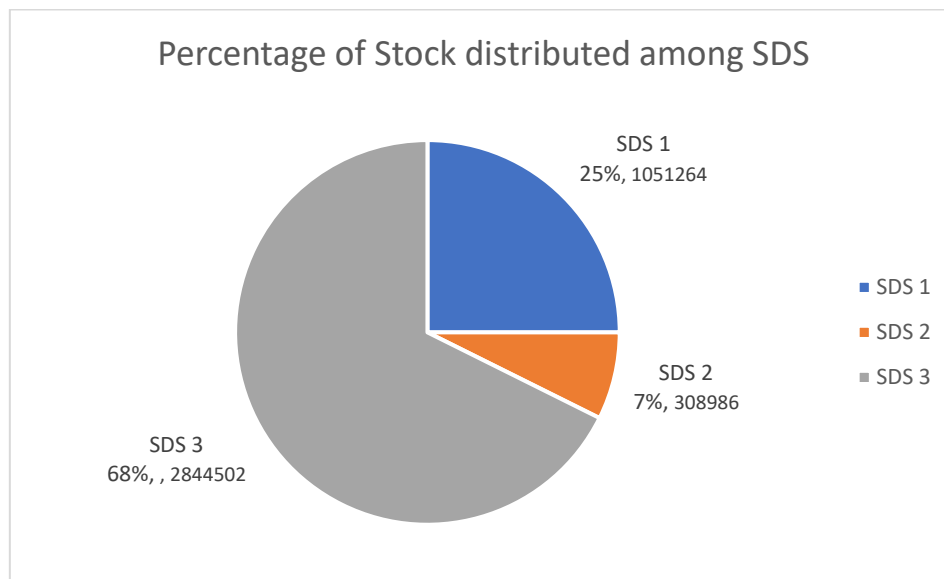


Figure 10: Distribution of Total State Stock of **Second-Line Anti-TB drugs** among SDSs in Maharashtra

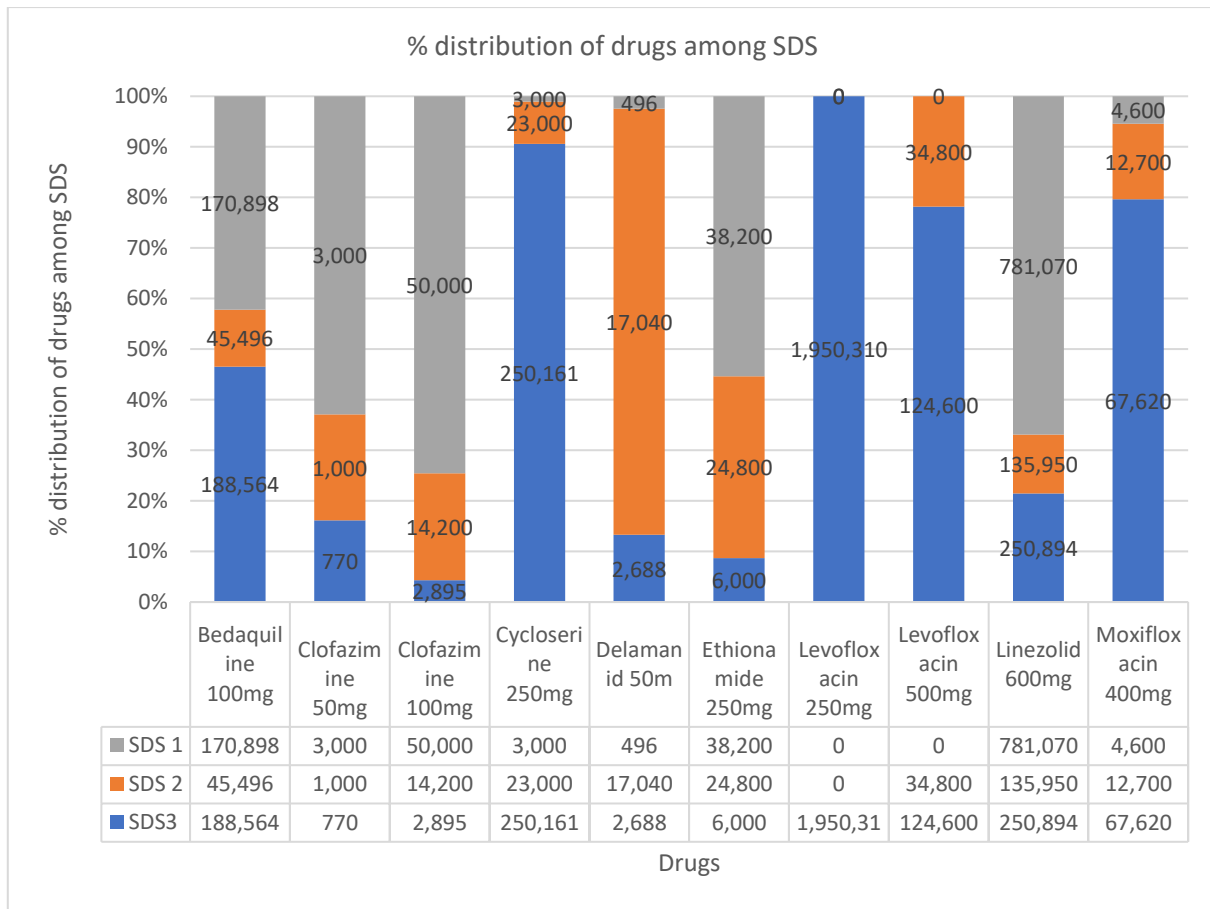


Figure 11: Distribution of second-line anti-TB drugs among SDS in Maharashtra

As shown in Figure 12, for most drugs, the “Indent Qty Placed” is significantly lower than the “Indent Qty Calculated”. The only exception is Cap Cycloserine, where the placed quantities are almost equal to the calculated quantities. On the other hand, an indent for Ethionamide was not placed in the study period due to an oversupply of the drug at SDS1 which was sufficient for more than 4 months.

Only 4% of the indented drugs were received from the CTD as depicted in Figure 12.

Some medications, such as Levofloxacin 500 mg, Levofloxacin 250mg, Pyridoxine 50 mg, and Cycloserine, had no deliveries from the CTD in November 2023. Others, such as Delamind 50mg, Clofazimine 50mg, Clofazimine 100mg, and Linezolid 600 mg Tab, had fulfillment rates of less than 10%.

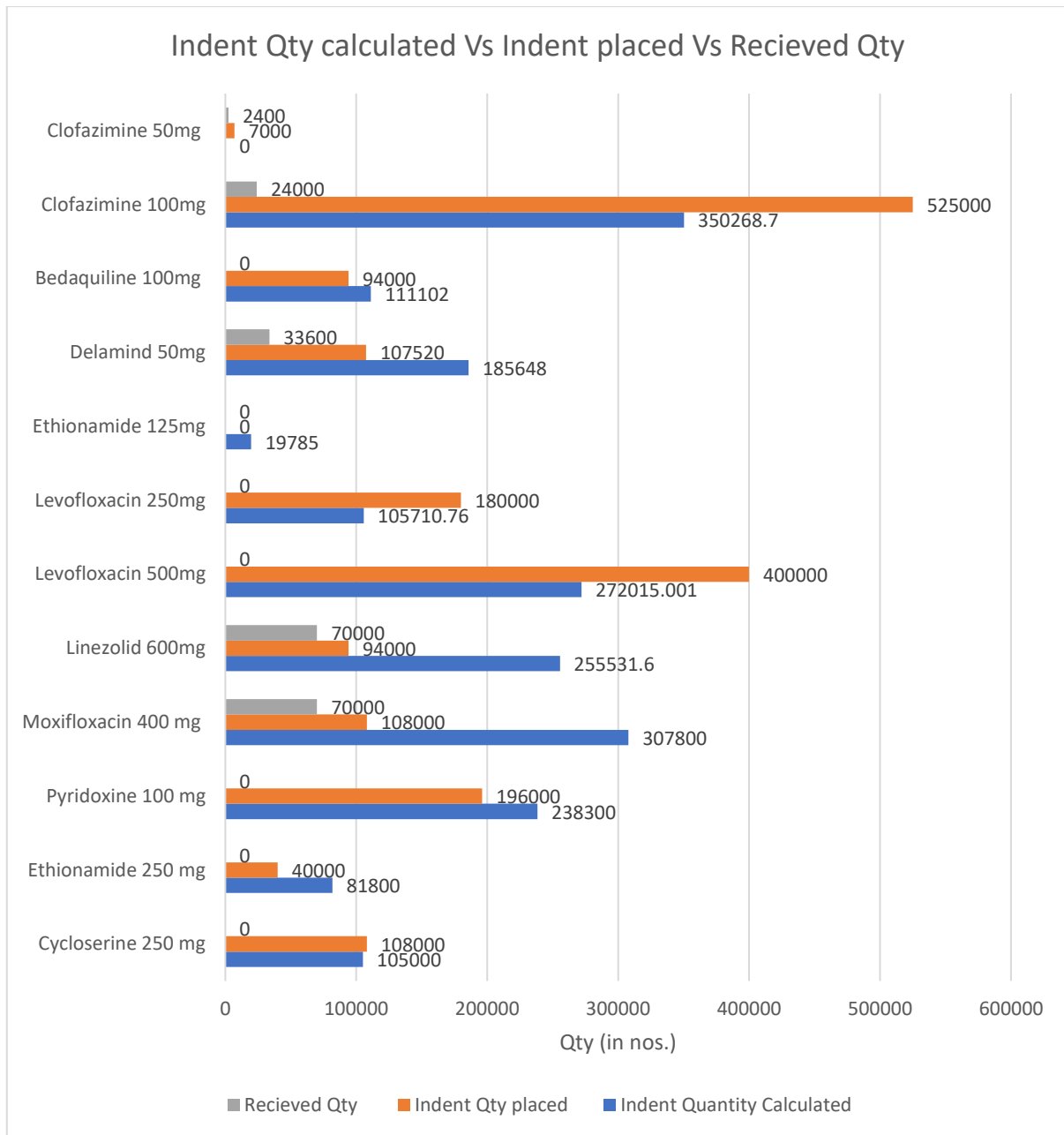


Figure 12: Comparison of the Indent Quantity Calculated with the Indent Quantity Placed with Actual Quantity received on ground.

Expired drugs at SDS1

Out of a total of 36,67,227 expired drugs, 1,16,079 are second-line anti-TB drugs of which 77,188 expired in 2022 as shown in Figure 13, because of surplus supply of short expiry, due to a change in drug regime protocol and delay in the disposal process of expired drugs. In 2018, the World Health Organization made an important change in treating MDR-TB by introducing drugs like Bedaquiline, Delamind, and Linezolid [9].

The delay in disposal of expired drugs is because Plan India had been recently given the responsibility for drug disposal, and due to delay in receiving permission from the central TB division leading to stockpiling and subsequent expiry of drugs while waiting for proper disposal procedures. Expired drugs are a concern and can be dangerous if they are used, and they can also take up valuable space in hospitals.

To estimate the cost of expired medications, a reference-based costing approach was employed. The last purchase price of a tertiary care teaching hospital as a benchmark was taken. Individual drug costs were calculated by multiplying the unit quantity with the reference price, and the total cost was obtained by summing these individual costs. The total cost of expired drugs is approximately ₹9 crore out of which the cost of second-line anti-TB drugs is approximately ₹3 crore, which is 33.33% of the total cost. The total weight of these medicines is 2860Kg and according to the pricing structure provided by Maharashtra Enviro Power Limited, the cost for disposal is ₹23.75 per kilogram. The projected expense for the disposal of these expired drugs amounts to ₹92,162 including GST and other associated charges.

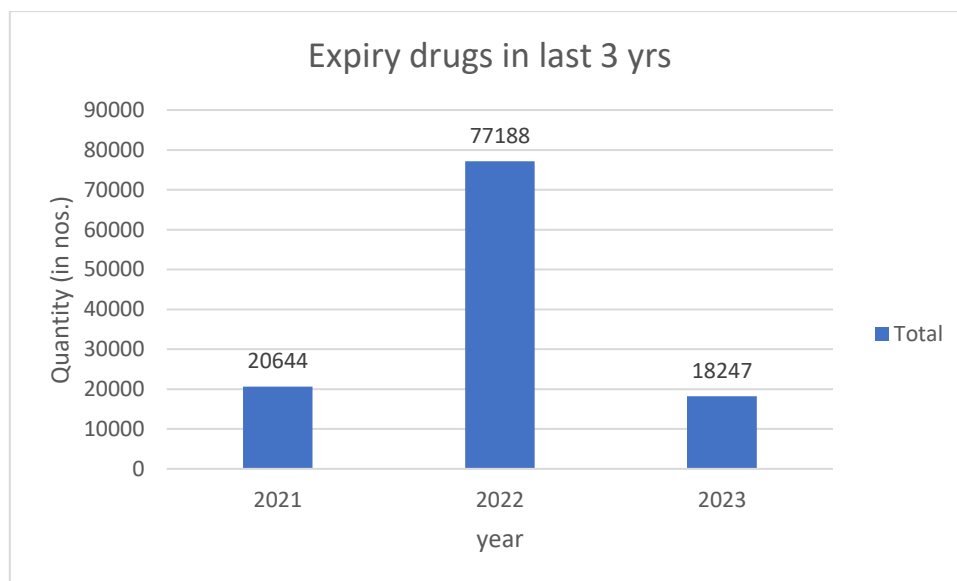


Figure 13: Expiry drugs in the last 3 years

Thematic analysis was conducted through unstructured stakeholder interviews to identify potential causes of stockouts for second-line anti-tuberculosis drugs and explore possible solutions.

Theme 1: Procurement and Supply Chain Management

Stockouts and Procurement – Stockouts are a recurring issue in the TB drug supply chain. One factor is the presence of near-expiry drugs at SDS. These near-expiry drugs lead to fewer requests for new drugs (indents), resulting in inventory shortages. Optimizing drug demand estimates to reflect actual healthcare system needs is crucial to address stockouts. Limited funding restricts SDS's ability to perform local procurement. In response, SDS delegates this responsibility to District Drug Stores (DDS). This allows SDS to focus on state-level inventory management while enabling DDS to address localized needs and potentially source medications from more readily available suppliers within their districts. However, delays in receiving drugs from the CTD create further challenges in maintaining optimal stock levels.

Expired Drugs and Disposal - The accumulation of expired drugs due to delays in disposal resulted from the new policy of Plan India and the supply of drugs near their expiry date by CTD. Implementing an efficient inventory management system that monitors expiration dates and facilitates timely disposal can be a solution and streamlining disposal processes with new policies can smoothen the disposal process.

Theme 2: Policy and regulatory limitations - Plan India is currently responsible for managing the disposal of expired drugs. However, Plan India has not secured the necessary permission from CTD to

execute the disposal process. This lack of authorization poses a challenge, impeding Plan India's ability to conduct timely and efficient disposal of expired medications. The current circumstance underscores the necessity for improved coordination between the assigned responsibilities of Plan India and the essential regulatory approvals from the CTD.

Theme 3: Financial resource constraints - Inadequate funding for SDS 1 limits local purchases and to address this issue has communicated to DDS to take charge of local purchases utilize the procured medications as needed and ensure timely distribution to Public Health Institutions (PHI). The estimated financial burden of expired medications at ₹9 crore, with ₹3 crore (one-third) attributed to second-line anti-TB drugs. Considering additional disposal costs of ₹92,162 for 2860kg based on Maharashtra Enviro Power Limited pricing, these findings highlight the substantial financial impact of expired drugs, warranting improved inventory management and cost-effective disposal solutions.

Theme 4: Potential Solutions and Improvements –

- A. Indent Optimization:** A comprehensive review and adjustment of indent quantities based on actual needs is crucial. This involves analyzing past consumption patterns, current demand trends, and forecasting future requirements.
- B. Increased Local Procurement:** SDS should seek increased financial support from higher authorities to enhance local procurement capabilities for essential drugs. This strategy minimizes reliance on centralized procurement channels and reduces vulnerabilities to delays or disruptions from CTD.
- C. Outsourced Pharmacy Function:** Outsourcing the pharmacy function can bring several advantages. The District TB hospital can focus on core healthcare services while ensuring that drug procurement, inventory management, and dispensing activities are handled with optimal efficiency.
- D. Disposal Policy Clarification:** SDS should collaborate with CTD to thoroughly clarify and streamline the existing disposal policy via Plan India. Policy changes should prioritize timely and efficient disposal, emphasizing safety and adherence to environmental regulations.
- E. Alternative Disposal Methods:** SDS should explore alternative disposal methods that align with regulations, assessing their viability and suitability.

3. Discussion

The pharmaceutical supply chain plays a strategic role in health systems, and understanding its challenges can aid healthcare managers and policymakers in enhancing system performance. s

In line with the results of our study, the findings of a study by Otuto Amarauche Chukwu et al highlighted the significant challenges faced in the supply chain management of medicines in Nigeria. Indicators of poor performance included uncoordinated logistics systems, weak forecasting, regulatory concerns, and a lack of support for in-country medical logisticians. The lack of standardized practices, poor regulation, and inadequate resources contribute to the inefficiencies in the system. To address these issues, there is a need for improved regulation, certification of practitioners, support for local drug manufacturing, and capacity building for pharmacists. Implementing effective policies, and investing in the Supply Chain Management of medicines are crucial steps towards ensuring better access to quality and affordable medicines in Nigeria. ^[10]

A study by L Bam et al, conducted in South Africa showed similar results to our study wherein the Amikacin supply chain exposes challenges like high inventory levels and extended supplier lead times, causing an estimated 19,200 shortages and \$880,000 in costs. The study advocates for efficiency improvements in the entire downstream supply chain, facilitating adaptability to tuberculosis drug demand

fluctuations by proposed safety stock policy, averting stock-outs without excessive holding costs, by advising stakeholders in tenders to weigh both drug unit prices and costs tied to longer supplier lead times. [11]

4. Limitations

The study only focused on 01 x State Drug Store (SDS) and did not collect data from the other two SDSs and DDS which limits the generalizability of the findings. The data was collected over four months (October 2023 to January 2024), which may not be sufficient to capture seasonal variations or long-term trends in supply chain management including challenges.

5. Conclusion

The study on the second-line anti-TB drug supply chain at State Drug Stores identifies challenges, including medicine stockouts and delayed disposal of expired drugs, funding inadequacies, and discrepancies in stock management practices emphasizing the need for enhancements in procurement and distribution processes to ensure the timely delivery of essential medications for tuberculosis treatment.

Conflict of Interest: None

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Figure Legends

Ser. No	Contents
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